Governance Workgroup
Draft Transcript
December 2, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good afternoon, everybody, and welcome to the Governance Workgroup. This is a Federal Advisory Committee running from 4:00 to 5:00 p.m. Just a reminder to workgroup members to please identify yourselves when speaking, and there will be opportunity at the end of the call for the public to make comment.

Let me do a quick roll call. John Lumpkin?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
John Glaser? Laura Adams? Leslie Harris? Christine Bechtel? John Mattison is on, but he's on mute. Linda Fischetti?

Linda Fischetti – VHA – Chief Health Informatics Officer
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Michael Matthews?

Michael Matthews – MedVirginia – CEO
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
John Houston?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Carol Diamond?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Wes Rishel will be on and off a little bit. Tim O'Reilly? Mary Jo Deering?

Mary Jo Deering – ONC – Senior Policy Advisor
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
Mariann Yeager?

Mariann Yeager – NHIN – Policy and Governance Lead
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Did I leave anyone off? Okay. I'll turn it over to John Lumpkin.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thanks, everyone, for doing the … session of what we signed on for, following our discussion at the HIT PC. What we're going to try to do today is to review the documents in preparation for the December 13th meeting of the HIT PC. What we've done in these documents, and what you'll see is that we are trying to bring back to the Policy Committee, at their request, clearer areas where we think that they ought to make decisions, and so, as you can see in a few of our slides, we have a number of options that are listed. What we would like to do with those particular slides when we get to them is to make sure that we've included all of the relevant options. Are the pros and cons fair? Then to give some indication of what our workgroup's recommendations would be to the Policy Committee on which option to select. Any questions before we get started?

Christine Bechtel – National Partnership for Women & Families – VP
John, I'm sorry I joined about two minutes too late, and so I may have missed this, but one of the things I know we talked about at the Policy Committee was the attributes of the organization that we talked about, the NGO. I didn't see that reflected on the slides, but did I miss it?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Actually, it's not on there because, as we were working through that, as you will see in the slides, the organization that we talked about as the NGO as sort of the third option, we've kind of pulled that off of the table by and large. I don't know if you've had a chance to walk through the slides.

Christine Bechtel – National Partnership for Women & Families – VP
Yes, so the option three, which is the semi-delegated development, federal guidance, and approval, that's what you mean?

Mary Jo Deering – ONC – Senior Policy Advisor
Christine, what you'll see in some of the options, especially around validation, but also probably around the COTIs is the possibility for some outside entities to play some specifically prescribed roles.

Christine Bechtel – National Partnership for Women & Families – VP
I think we talked about the NGO leaving validation aside. I think the concern certainly that I raised, and I think others have raised, has been around the prioritization and establishment, particularly establishment of the COTIs. John, when you were talking about the third option, I'm looking at slide 33 that has the process for establishing it. You're saying, I think, that option three was the kind of NGO approach that we had previously recommended, but now it's off the table and we're thinking more about either rulemaking or a federally facilitated process. Is that what you're—?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
No. Why don't we wait until we get to that slide?

Christine Bechtel – National Partnership for Women & Families – VP
Yes. It's just that something is on the agenda regarding this is all I'm trying to establish.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Right. Something is on there, but not necessarily because we're looking at options that we want them to decide, and I think it's premature to go into the attributes if we, as a workgroup, are not going to recommend that option.

Christine Bechtel – National Partnership for Women & Families – VP
Great. That makes sense. Thank you.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Any other initial comments? What I'm going to do is suggest that we jump ahead to slide number 25. All the slides that are up until then—unless anyone has any comments on those slides—are pretty much things that we've gone through before, going back to the detailed description of the principles, which were our phase one recommendations. Then you'll see in slides 18 and so forth what we found based upon the hearing and other considerations of the committee and the public input. Then that gets us to slide number 25, which are the general recommendations. These are the recommendations that we have presented before, and just want to see if there are any issues or concerns on slide number 25.

Slide number 26, which goes back to the recommendations that we had before on federal responsibilities. The federal entities would be expected to meet the conditions of trust and interoperability, that we would be leveraging existing mechanism, and this is the one that we've done a little bit of refinement on existing state authorities across all relevant domains should be recognized, and the needs for coordination and harmonization be identified. Any thoughts or comments on that one?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
With regards to that third bullet point, I guess the question I have is learning from the experience with respect to HIPAA, this idea of right of things like preemption and more stringent, I sort of get a little worried when I start to see interaction with state authorities. Is there some idea or some notion of priority or overarching authority structures when you're in this case?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think that the potential for that is going to be dependent upon law. What basically was established because of the authority granted under HIPAA was the floor of preemption on privacy related issues. What we're talking about in governance is not specific authority in that regard, so I think we're looking at the role of the federal government to coordinate between those activities. Ideally that with the federal government getting out, maybe not ahead of Minnesota or New York, but ahead of most states, that that will set the framework for which they will look at governance of exchange within their jurisdiction.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I'm still having problems with that. What you're saying is that the state authorities really will provide some type of initial guidance as to how we're going to set this up? Is that what you said?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
No. What I'm saying is, and Mary Jo and the Feds on the line can help us. There's no clear authority, as far as I understand, to preempt state law as it relates to governance.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I'm just concerned that if that's the case then we're going to have a real problem making some type of rational governance structure that's going to allow the NHIN to be effective.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I agree with you. I think that the challenge then is to get a mechanism in place where the federal government is playing a role of setting up what that structure can be, and my experience at the state level is that the first thing you do is you look for what's existing infrastructure before you start trying to reinvent the wheel. With that in place, what we heard from Minnesota was that they have put this structure in place, but most states will, I think, look to the federal government. If there's something in place, model their state law around that.

Mary Jo Deering – ONC – Senior Policy Advisor
John, could I clarify for both Johns actually? Actually, let me clarify as John Houston, first of all. Do I understand you to say that you would actually prefer to make some kind of a statement of a more affirmative nature about the need for consistency across states in this way?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I believe yes.

Mary Jo Deering – ONC – Senior Policy Advisor
Okay because I would only suggest that this phrase, as you see it on slide 26, is obviously very carefully crafted because ONC cannot—as John has said—overtly preempt state law. But I think, and you are both experienced FACA members, to the extent that you have that the workgroup should determine that it sees a need for some strong, would like to take a policy position on that, I mean, it's my assumption that that's perfectly within your rights to voice your views on what would be optimal.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I'm not sure I agree that we can't preempt or we can't provide a federal framework because this ultimately, I think, falls under interstate commerce, which is within the purview of the federal government.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Basically, I think what you're suggesting is that we would then take what we have under point number three as existing authorities across all relevant domains should be recognized and needs for coordination and harmonization identified. To the extent of the law, a federal coordination should be enforced.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Or required, yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes.

Mary Jo Deering – ONC – Senior Policy Advisor
Just to capture that, and to the extent permissible by law, did you say?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes.

Mary Jo Deering – ONC – Senior Policy Advisor
I guess you'll probably culver some discussion on that, but I just wanted to make sure I got it down.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I'm just thinking conceptually. If there's a better way to state it, I'm just bringing up the concept, the concern.

Michael Matthews – MedVirginia – CEO
John, I'd like to weigh in on this. I'm somewhat confused by the last few minutes of conversation around this one. It seems to be taking us down a different track than we have had discussions before. To have consistency across states implies that states are having consistent approaches to their needs and capabilities and interests. I thought where we had gone with all of this is to say here are the various modalities within which the NW-HIN activities could occur, and a state can choose to play by those rules of engagement, whether it's Exchange or Direct or zebra, and then they would either conform to that or not. The issue of the preemption and what's federal and so forth and interstate commerce, I'm just not understanding how we got there based on where we started at with the NW-HIN governance structure to oversee and direct policy for the various activities that would be subject to that overarching governance structure.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
If I can just sort of help try to clarify, I think we have to look at what states might be doing in two contexts. One is the state as the host or sponsoring body for an exchange entity, and the second, as we saw when we heard from Minnesota as a governance entity that is setting up the requirements within the state how trust and interoperability is established, what are the requirements for participation, how exchange should occur. It is the latter situation that sets up a potential for lack of consistency in how governance occurs from one state to another, as opposed to looking at exchanges participating under state authority.

Mary Jo Deering – ONC – Senior Policy Advisor
To put a fine point on it, this is not about the technologies or the architectures per se. It's about more the governance aspects of non-technical, in the non-technical sphere.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Correct. Does that clarify?

Mary Jo Deering – ONC – Senior Policy Advisor
Does that help, Michael?

Michael Matthews – MedVirginia – CEO
No. I'm trying to be clear about my confusion because what I think we're now talking about is some sort of extra territoriality beyond the states' borders, which I thought was beyond the domain of what's on the table with our overarching governance. MedVirginia shows up. Montana shows up. Minnesota shows up. How they manage within their own jurisdictions is their business, but how they then engage and comply with the rules of the road that have been defined or will be defined for the Nationwide Health Information Network or NW-HIN, whatever we end up calling it, to me is what's being discussed here. Again, I think we're introducing something new that's bleeding the state issue into all sorts of other dimensions that we hadn't contemplated. I don't see where a Minnesota or Montana is any different than MedVirginia in terms of the requirements to comply with the policy framework, standard specs, etc. that we're establishing for NW-HIN and all within the context, of course, of devolution.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I don't think we're on a different page from what you just described. I'm only worried at the point when everything has to try to roll up at a national level. If states want to do things within the states, and they choose to do them however, I don't think we have any control or right to discuss how that happens. But I think the problem is when we're dealing with how then the interaction has to occur between states as it all rolls up. That's when I think that I'm concerned that we have to be careful not to— There's a fine line between having that occur and then having sort of this same issue that occurs with HIPAA occurring whereby you end up having confusion because there are so many variations.

Michael Matthews – MedVirginia – CEO
I agree with those points, John. My issue is not with that point. I guess my issue is more related to just the third bullet around existing state authorities. I think it just introduces for people … spent the hours at the table that we've spent on this thing is going to introduce a lot of confusion when the states show up to participate in the various activities that they will be unable to do so exactly what the expectations are, what are the requirements for participation. Then we get into the COTIs, etc. But to me this is a fundamental component of setting the expectation that, again, whether it's MedVirginia or Virginia or Montana or Acme HIE in Spokane, that we've got the consistent requirements that are going to be imposed for those people that want to play in that particular domain.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think the issue here is whether or not the statement that we have here, which is fairly consistent with what we said before, is strong enough, or whether we need an additional statement saying that more active engagement by the federal government to assure that there is harmonization across states occurs.

Linda Fischetti – VHA – Chief Health Informatics Officer
Michael, if I could ask a point of clarification, you were trying to point out that this is an edge system and doesn't need to dictate what happens in the state. It really only applies to conformance at the edge. Is that what you're trying to say?

Michael Matthews – MedVirginia – CEO
I think I understand that, but define edge in this case for me, Linda.

Linda Fischetti – VHA – Chief Health Informatics Officer

Meaning that the policies would need to be complied with when they interact with NW-HIN, but then those policies don't need to be native to the states.

Michael Matthews – MedVirginia – CEO
Thank you. Yes. That's it exactly.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Can we interpret what we have in three as saying that, or do we need additional language?

Mary Jo Deering – ONC – Senior Policy Advisor
Elsewhere, I'm wondering if it still shows up. In our previous presentation, we did specifically call out issues where state policies or the actions of private entities create barriers to exchange.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes.

Mary Jo Deering – ONC – Senior Policy Advisor
That was our catch point.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
It is ….

Mary Jo Deering – ONC – Senior Policy Advisor
I think it still shows up in slide 36, I think, although actually, let's see if we— See, I'm afraid that we took it out of the text. It used to be in the explanatory text that preceded what would be slide 36. There it is. No, yes, at the bottom of slide 36.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Address circumstances where state level efforts or private actions create barriers to exchange that require affirmative action. John Houston, is that what you were talking about?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Is it okay with you if we leave the language here and then come back to it when we get to 36?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
That makes sense. Sure.

Mary Jo Deering – ONC – Senior Policy Advisor
I think also you'll see it on the technical level when you talk about validation where the example of the flow down. We talk about the flow down between Feds and states into other places as well.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Unless we have any other comments on slide number 26, can we move on to slide 27?

Linda Fischetti – VHA – Chief Health Informatics Officer
I have one question on slide 27.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes.

Linda Fischetti – VHA – Chief Health Informatics Officer
My apologies. I missed this the last time that we met, so this is on the first bullet, and I just want to ask the opinion of the group. Do you interpret the first bullet that ONC would be coordinating all of the federal

activities, and then ONC would be the representative for all the Feds into the NW-HIN governance or do you believe that that bullet does not preclude that? Because as a national healthcare provider, we certainly would want to have the ability to fully participate in the governance of NW-HIN in such a way that we were a fully invested participant with our partners that we deal with in all of the different states and all of the different vendor partners?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I actually see that one as being agnostic on that issue, speaking neither for nor against it. It just talks about a coordination role.

Linda Fischetti – VHA – Chief Health Informatics Officer
Excellent. There is a need for federal coordination. They certainly need to make sure that VA doesn't start publishing its own interoperability standards or something silly like that, so a federal coordination role that does not preclude federal engagement s our own individual departments with NW-HIN. Thank you.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Other comments? The items in red are the ones that you have not seen on this slide. You'll recognize the first one in red, which we again had much more significant discussion about an NGO, and one of the rolls was to optimize input from a broad range of stakeholders. We've moved that into the federal responsibility based upon the comments that we've heard and discussion at the Policy Committee. Beefing up that role also is the last item of doing evaluation of the governance.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
The middle one, it says authorized, shared, technical resources, shared technical resources means what?

Mary Jo Deering – ONC – Senior Policy Advisor
It could mean like provider directories, for example. So should there come a time when there's a directory or some other types of service that is recommended and that would facilitate broader interoperability, and we want to recognize it and deem it as a shared resource. There has to be some means to bring that forward and say, is this a good candidate to be proposed as a shared resource? It's a little different from the type of certification or accreditation that happens with regard to an entity, but it's still something that needs a process.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
You used the phrase technical resource and resource. Is technical necessary as part of that phrase, or is it always a technical resource?

Mary Jo Deering – ONC – Senior Policy Advisor
Mariann, do you want to jump in here? Certainly, that was how— There's a very clear need to do it for technical resources. I guess I hadn't thought so much about what might be a non-technical resource. Mariann, do you have any comments on that?

Mariann Yeager – NHIN – Policy and Governance Lead
I need to think about it a second. I mean, definitely, there are clear examples on the technical side. The question is, is there anything that's not technically related that wouldn't be otherwise addressed through requirements. This process is essentially identifying where there may need to be things that are adopted for use in an NHIN environment or a NW-HIN environment that may not be covered in the technical requirements and specifications or policies.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So the question is whether or not technical adds value to it or if we can say shared resources. That gives us the most amount of flexibility, as the NHIN evolves. Are there any objections to removing the word "technical" in the sixth …?

Mary Jo Deering – ONC – Senior Policy Advisor
Could it inadvertently cause questions and raise concerns because it was so broad? I don't know. I just wanted to put that on the table.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Any concerns about that with the group, or can we eliminate that word?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I just wanted to know what that meant, and I could take it or leave it.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Then we'll leave it. We'll leave it the way it is. Any other comments on page 27?

Michael Matthews – MedVirginia – CEO
Third bullet point, optimize input, please clarify what that means.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
This would mean that we would, as we discussed it, one of our principles is that there'd be input from a broad range of stakeholders, including consumers. That's language we've used a fair number of times. That may be through the FACA process. It may be by, as we have done with this committee through the use of blogs and other kinds of means. But that we would see that this would be a role that ONC would play.

Michael Matthews – MedVirginia – CEO
Then how does this relate to what's coming up, I guess, on slide 36, the coordination role? Is this coordination, or is this one way?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I'm not sure. I would not see this as being a coordination role. This is just saying that we believe, as a principle, that there needs to be a broad range of input. As we have identified the policy setting role for the federal government, we encourage a broad range of input as they're developing that policy related to governance.

Michael Matthews – MedVirginia – CEO
I'm good.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Anything else in 27? Let's move on to 28. The COTIs: This talks about the process. The change you can see in red. The first is that we said that we were probably more directive on the third hash or dash, and so we've just put in a little bit of waiver that there may also be that COTIs that are required in particular circumstances. Then the fourth dash sort of follows some of the input that these things should be rigorous, measurable, and enforceable. Any comments on page 28?

Moving on, 29, I think we've seen and gone through. We can probably go now to page 31, unless there's anyone who wants to stop us going. This is just what we will be focusing in on. There are three issues: the conditions of trust and interoperability, supporting federated governances approach, and establishing the invalidation. These will be the three areas where we will present options.

On the first issue, page 32, how should the conditions of trust and interoperability be maintained, and how should they be addressed? What you'll see on slide number 33 is the two tasks: Establishing an initial set of conditions of trust and interoperability and maintaining, as a second task, these, once they've been initially established. This would include both keeping the conditions of trust and interoperability that are currently in place, keeping them current, replacing any that need to be replaced, or retiring those that require or establish new ones for issues that weren't clear when the conditions of trust and interoperability were initially set up.

There are three options, as you can see on there. Option one entirely through rulemaking. The second one would be a federally facilitated process where they'd be established and ruled as categories of conditions of trust and interoperability, and then a federally facilitated process for developing and improving the conditions of trust and interoperability.

Mary Jo, if you could help us with what federal facilitated process means.

Mary Jo Deering – ONC – Senior Policy Advisor
Actually, we almost struck that out. I think the distinction there is very strong federal leadership, that this is a process by which, regardless of how many steps end up being required in identifying, prioritizing, and developing the conditions that all of those steps would be basically guided by the federal government. The distinction between two and one is the endpoint, is largely the final step of the process in that – well, actually, let me take that back. They have two. Option one and option two probably have two major distinctions. The first major distinction is obviously that the final product, you know, the final condition are accepted, announced through the formality of a rule, through the NPRM process. Each time they are put out under an NPRM first for guidance and input, and then subsequently in the final rule. That's one key distinction.

I think the other distinction is that option two says that you will actually, in this governance rule, set up, you could call it, a gold-plated process. You could actually specify the exact steps by which these would be developed and brought forward, and then the final step would be actually named in the rule, but the final step would not require a rule. Does that make sense?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Do we have any examples of that?

Mary Jo Deering – ONC – Senior Policy Advisor
For example, when we wrote our recent certification rules or when the meaningful use was established, there was the very formal process of seeking input through FACAs and then the agencies themselves just basically took that information inside the agency walls and produced an NPRM. Then there was another opportunity for input, and then the agencies take that under advisement inside their walls and produce the final rule. Whereas, in process two, I think that the certification program is more like that, as I understand it, and I don't want to get too far out ahead of myself because we'll get to that when we get into the validation option. But I think you would consider it as saying that there shall be steps A, B, and C by which input shall be collected, nominated. New conditions may be nominated. They would be considered and reviewed through such and such a process with such and such input. And at the end of their full development and review stage, the final step shall be that they will be published in the federal register for 30 days of comment. Again, I'm sort of making this part up, but that's what this second option could look like.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Then the third option is the one that ….

Mary Jo Deering – ONC – Senior Policy Advisor
The third option would be very similar to option two with the difference that as happens with, as I understand it, HIPAA and SDOs, and remembering that some of our COTIs are technical in nature, that you acknowledge or even overtly delegate to some outside entities, existing or not, some particular steps in the process, but you have set the requirements for the process. Again, I think we're all familiar with how that works in standards. Linda was very helpful in reminding us of the OMB language there. For example, that on the standard side, the interoperability side, there are processes that these outside organizations have to go through to be recognized as able to bring forward these recommended standards. It would be very similar to that process.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
What we have, we have three options here. Are there options that are—? Let me first say, are there any other options that should be on this list?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Just one question about, is this sort of mix and match? Can you have option one for establishment and option two for maintenance?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
We can make that recommendation. Yes.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
That's my only comment then.

Laura Adams – Rhode Island Quality Institute – President & CEO
Just one thought I had on this was I think the notion of facilitation versus delegation is a little fuzzy, and I'm wondering if it's a federally led process, or does that term imply other things that we don't mean to imply with option number two? It feels to me like the differentiation between option two and three has to do with really the federal, the leadership that's happening at the federal level of this under option to, to a greater degree, and there may be some delegation. But it's ultimately led.

Mariann Yeager – NHIN – Policy and Governance Lead
Mary Jo, did you want me to …?

Mary Jo Deering – ONC – Senior Policy Advisor
Yes. By all means, you can jump in.

Mariann Yeager – NHIN – Policy and Governance Lead
I think the primary difference between option one and option two is that how ….

Mary Jo Deering – ONC – Senior Policy Advisor
I think she said about option two and option three.

Laura Adams – Rhode Island Quality Institute – President & CEO
Correct.

Mariann Yeager – NHIN – Policy and Governance Lead
Right, so option three is basically where the federal government would facilitate getting public input in defining the COTIs. It's the process itself for developing those that will be put forward in the rule that would allow ONC or the federal government to establish the COTIs through public input in its own development process, but not having to establish the COTIs in the rule itself. Option three is delegating that and using some other vehicle to get that input and possibly helping with the definition of it, but bringing them back to the federal government to approve them.

Christine Bechtel – National Partnership for Women & Families – VP
But, Mariann, where I'm struggling is it seems to me like option two could really end up being option three if what you do is lay out in an NPRM, which would have public comment, a semi-delegated development process anyway, right?

Mariann Yeager – NHIN – Policy and Governance Lead
I guess it could. The assumption for option three is that it's building on option two and taking part of what is done in option two. Option two is really the federal government does it all.

Christine Bechtel – National Partnership for Women & Families – VP
That's not what I'm reading though, so what would a process where the federal government does it all, but it's not through rulemaking at that point, what would that process, what could that process look like?

Mariann Yeager – NHIN – Policy and Governance Lead

I think some of the, just as a … example is, there could be a process established in the rules for public input to be sought. There could be input from the FACAs. There could be input through public comment periods. There could be ….

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Let me sort of jump in here, if I can.

Christine Bechtel – National Partnership for Women & Families – VP
But ….

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Yes. Hold on. I'm suggesting that if we, sitting here on this workgroup, can't actually clearly delineate the difference between option two and option three, it will be even more difficult for the Policy Committee to do that. What I'd like to suggest is that we eliminate option number two.

Christine Bechtel – National Partnership for Women & Families – VP
But, John, there is some significant appeal to option number two if we understood, beyond what the rest of the list that Mariann was rattling off the top of her head was because, Mariann, if I'm following you right, a public input process is definitely a rulemaking process. Yes, you can use blogs, but there's the public rulemaking process. There's a FACA process, which has a public input dimension.

But I'm trying to get at— I think what would be helpful for me is if we could step back and think about or maybe staff can come back with what are the options that you have at your disposal in that federally facilitated process. Because, from what Mariann was saying, I'm also not sure I can totally distinguish between option one and option two. Because what Mary Jo laid out early around the meaningful use process, I would probably have categorized the meaningful use process as option number two because it wasn't just pure rulemaking where the agency is inside its walls and stays inside its walls.

Mary Jo Deering – ONC – Senior Policy Advisor
Right. But I think that was where I tried to make two primary differences between option one and option two. The first absolutely rigid difference is rulemaking. If the workgroup feels strongly that everything about either the initial establishment or also the maintenance of the conditions is so vital that it needs to be conducted through formal rulemaking and that nothing will become official until it is put through an NPRM and a final rule, then you would vote for number one. There's no doubt that, as part of that process, you could get additional input beyond just the FACAs. You're absolutely right. But that primary distinction is that you would require the full formality of the rulemaking process and the con, which is spelled out there, is the time implication and the fact that it's not nimble. Again, the workgroup could feel strongly that that level of formality is needed.

Christine Bechtel – National Partnership for Women & Families – VP
But that's almost an enforcement question for me.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Carol?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. Thanks. Sorry, Christine. If you want to finish, go ahead.

Christine Bechtel – National Partnership for Women & Families – VP
No. It's almost an enforcement question, so I'm trying to understand the question ….

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I agree with that. I am also confused here because rulemaking may be an aspect of each of these, and I think one of the things that's confusing me in thinking about this is, are we trying to solve every element of the conditions for trust and interoperability with a single process? In other words, the process for privacy policy may be very different than the process for a new specification for submitting a meaningful use quality metric. I think, depending on what you have in your mind when you look at this, you could read each of these very differently.

Mary Jo Deering – ONC – Senior Policy Advisor
If you remember back on slide … the one that laid out the potential … I think it's slide 29. There was an example of the types of things that would be happening. I think you're quite right. And ONC has already begun to discuss that in that one way or the other, the policy work of coming up with what exactly you want in terms of privacy and security requirements is a process in and of itself that has certain requirements and certain steps. I do think we agree with you on that, but it's perhaps the process of bringing them together, of recognizing them as a condition that ….

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Right, but I don't think you can simplify how they're established or maintained as though they are all necessarily merit the same process. I don't see how they would.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Carol, I think what you're raising right now actually helps me differentiate between these options. Option one is you basically treat them all the same. All the COTIs are treated the same because they all go through a federal rulemaking process that's completely within the FACA or whatever. Option two says that the rule that would be adopted would describe the pathway for different types of COTIs. Then, based upon what kind it is, it will go through a different pathway, which will be facilitated by the federal government. Option three takes that a step further and says that some of those pathways can be delegated and others may not be.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Are we saying that rulemaking is potentially a mechanism in option two?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think, as I'm now listening to you and interpreting it, I would say that rulemaking would be an option in all three. In addition to rulemaking, the rulemaking may be very specific in each one of these options or, in option two, it may say that there are a set of COTIs or a range of COTIs for which the rule that will be published will not be as specific, as much as it says how those COTIs are created. Then the federal government would be responsible for running that process of creating those COTIs.

Christine Bechtel – National Partnership for Women & Families – VP
John, I think that's good logic, and where I'm struggling is I think that applies to certainly the establishment in particular and potentially the prioritization, but possibly not the maintenance necessarily.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I can't remember if it was John or Mike who suggested that we may want to suggest one option for the first set and then a second option for the second.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
I'm allowed to have one good idea a day.

Christine Bechtel – National Partnership for Women & Families – VP
Good job, John…. It may make sense to really break this out into a deeper grid or something that says, okay, if we're talking about establishing them and potentially prioritizing them, there's this, and then if it's maintenance, there's this. But either way, that option two gets redefined as John described it, which is the federal government leads the process, which I like the idea of publishing the process that the government is thinking of for particularly the establishment and the prioritization of the different COTIs, but that the government leads the process of figuring out which process to use.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Right. I'm reminded that we are only able to go until 5:00 today.

Christine Bechtel – National Partnership for Women & Families – VP
Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
We will, I think, only be able to get this to resolve this slide. I would suggest that people take a look. No, actually, it's just this slide and issue number one. The way that I think that we've refined our understanding of option one, two, and three, given that, are we comfortable in saying which one we would recommend to the Policy Committee.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I really don't understand fully the difference between them, and I also think if option two is you find the one that works or the one that matches with that particular condition, then we're talking about a hybrid of all three. Therefore, I really don't understand the distinction.

Christine Bechtel – National Partnership for Women & Families – VP
Yes. I also wonder if it would be helpful to actually suggest some kind of parameters for what the workgroup thinks in terms of the kinds of characteristics for a COTI that might lend itself to a different part of the process. If you're going to do new privacy policy, there's probably got to be a rulemaking on that for sure, right? It may not be that we would say that, but that we would say that there's much more robust public input for certain kinds of COTIs than others, and what might those be. But I think it's a good idea to step back and do maybe a deeper dive that's not limited to a single slide because I think it's just hard that reflects the conversation that we've just had and gives us an opportunity to comment on that.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Let me suggest that what I'm hearing is that a point of agreement is that not all the adoption of—let me see if I can say this in a way that's not a double negative—that we believe that there are multiple pathways to adoption of COTIs. That the adoption process can indicate that the first step is to publish a rule saying what the pathway is for each one of those classes of COTIs. Then the next step would be then to implement that, and that may be through a process that looks like option three. It may be a process that looks like option two, or it may be a process that looks like option one.

Now by saying that, you're saying that we are comfortable with— If we were to say that, we would say we would be comfortable with some delegation of the development process. If we are not comfortable with that delegation, then we would say that what we're looking at is basically an option that says there will be a rule that says how they will be adopted. Some may be adopted directly, and some may be through a facilitated process, as described in option two. Then we would ….

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Why is that? Why couldn't a rule say something is going to be delegated?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I'm comfortable with that. I'm just ….

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
But delegation is the distinction here, at least— I don't know. I'm confused.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Let me try again. There are three pathways to adoption. One is just done by a role. The second pathway is through a facilitated process. The third pathway is through delegation. That what we're describing as an approach is that the first step that would be done at the federal level would be publishing a rule that would establish those pathways. In other words, which set of COTIs would go with which pathway?

Christine Bechtel – National Partnership for Women & Families – VP
Which, John, I think makes sense, but I still don't understand the second pathway. That's my problem.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Which is the facilitated pathway.

Christine Bechtel – National Partnership for Women & Families – VP
Yes. I don't really know what that means.

Mariann Yeager – NHIN – Policy and Governance Lead
Just based on some preliminary discussion, it sounded like that there were other avenues available in the federal government to get input and put forward requirements. That the requirements themselves didn't have to be codified in a rule, but the process was sort of the solid, ironclad process itself that was vetted, and that the output of that could be a publication of standards, a publication of a list of requirements, policy requirements … existing requirements. But I think that was the primary distinction was option one, I think, as it was just put forward for the group, consideration was that the process for developing COTIs and the COTIs themselves would be codified in a rule.

Option two was the process for defining COTIs would be codified in a rule, but the COTIs themselves would be developed through a process led by and facilitated by ONC or whoever, and that there are various avenues available to the federal government that don't have to be through … comment rulemaking to publish requirements. Then the third option was to spell out delegation of that development in certain scenarios or whenever appropriate to someone else to do the development, but to have the process for developing COTIs codified in the rule.

Christine Bechtel – National Partnership for Women & Families – VP
I understood that, but what I'm suggesting that might be helpful is to understand what those other avenues are.

Mariann Yeager – NHIN – Policy and Governance Lead
Yes. We can definitely lay that out.

Christine Bechtel – National Partnership for Women & Families – VP
Great.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
We actually only have, by my clock, three more minutes, and we don't have the capacity to go past 5:00. We do need to get public comments. What we will do is try to clear up this language, get it out to the workgroup, and ask you to make comments, and then we'll need to have additional conversations to finalize that and then deal with issues two and three.

Mary Jo Deering – ONC – Senior Policy Advisor
John, just to point out, we only have one hour scheduled next week, and that's next Friday. I think it's 1:30 to 2:30.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I would ask that if we can do some of this through e-mail so that we can maximize the utilization of our time next Friday because that's the Friday before the 13th, which is when this is being presented.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
A quick question: are we really going to focus primarily on the red language, or is everything open for discussion, primary discussion?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Everything is open. We use the red language to focus in on those— I tried to get through the preliminary slides because we've been through them a bunch of times, and so we're really focusing on slides 33 through the end.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Okay.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
All the language.

Mary Jo Deering – ONC – Senior Policy Advisor
I would … we will bring out the additional detail, but if when you consider that, you do carefully read the examples of flow downs that we've given, especially when it comes to validation because it may be that there's a certain pattern that emerges that seems comfortable to you. Again, one size won't fit all, but I think that seeing how it could conceivably play out in other circumstances might be helpful.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
We need to see if there's any public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
Right. At this time, we'd like to invite any comments from the public. Operator, could you please give instructions?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Any final instructions while we're waiting to see if there are any comments?

Coordinator
There are no public comments.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Other than the plea of please watch your e-mail, and if you could be so kind so that we can try to get as many of these issues in a decidable format for our meeting on Friday.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, John.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thank you, all.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security
Thank you. Bye-bye.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Bye.